

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

<p>IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LIGATION</p> <hr/> <p>THIS DOCUMENT RELATES TO ALL CASES</p>	<p>Master File No. 2:12-MD-02327 MDL No. 2327</p> <p>JOSEPH R. GOODWIN U.S. DISTRICT JUDGE</p>
--	--

**PLAINTIFFS' STEERING COMMITTEE'S REPLY BRIEF IN SUPPORT
OF ITS MOTION TO COMPEL RESPONSES TO PLAINTIFFS'
FIRST SET OF INTERROGATORIES AND FIRST SET OF
REQUESTS FOR PRODUCTION FROM DEFENDANT ETHICON, INC.**

The Plaintiffs Steering Committee respectfully submits the following Reply Brief in support of its Motion to Compel.

I. Introduction

It is abundantly clear from Defendant Ethicon, Inc.'s ("Ethicon's") response to the Plaintiffs' Motion to Compel that Defendant has no legal support for the unusual manner in which it has responded to Plaintiffs' discovery requests. Defendant's approach has been to lodge vague objections, replete with boilerplate language, but then to produce some of the documents that Plaintiffs have requested. In Plaintiffs' Motion to Compel, Plaintiffs laid out three independent reasons as to why Defendant's improper approach has resulted in Defendant waiving its objections. Defendant's response cites no authority to the contrary. Instead, Defendant tries to shift attention away from its own failures by stating the number of documents it has produced, as if the Federal Rules excuse inadequate responses once document production hits a certain number. Of course, they do not. Further, Defendant tries to shift the blame to

Plaintiffs with the ridiculous assertion that Plaintiffs have failed to meet and confer, even though the parties have been going back-and-forth on these issues for several months, and even though Plaintiffs have consistently maintained that Defendant's practice of lodging boilerplate objections is unwarranted and contrary to the Federal Rules.

Meanwhile, Defendant's response ignores the fact that there are key documents that they have not produced at all, such as the initial label on the TVT-Classic product; that several other critical documents have been produced on the eve of depositions, or even in the middle of depositions of key witnesses; or that Defendant is continually moving the ball by designating certain important documents as "final" or "in use" versions, and then later changing the designations after these documents have been used in depositions.

In addition to further explaining why Plaintiffs' legal position is correct, this Reply will focus on the question of, why does it matter? After all, Defendant has produced a veritable haystack of documents. Broadly speaking, the issue is that the documents have been produced in such a way that Plaintiffs cannot make use of them—a fact surely not lost on Defendant. Plaintiffs are forced to piece together information, searching for critical documents within the haystack, only to find after hours and sometimes days of searching that these documents, though clearly within Defendants' Rule 26 disclosure obligations and the subject of a formal Request for Production, have not been produced.

Defendants' discovery violations are even more prejudicial given their timing. Though the first bellwether trial does not begin in the courtroom until January, the trials of the bellwether cases have already begun. Few, if any, of the Ethicon witnesses are within the subpoena power of the Court, and Defendant has given Plaintiffs no indication that it will voluntarily bring any requested witnesses to trial. Consequently, when Plaintiffs depose a particular witness, Plaintiffs

may be acquiring the only material they will be able to use from that witness in all of the bellwether trials. Under these circumstances, Defendants' unfounded practice of objecting while answering discovery should not be countenanced, because the practical effect is that none of the Defendants' discovery responses can be relied upon by Plaintiffs in depositions or at trial.

To further illustrate the issue, Plaintiffs are including examples of situations in which Defendant's inadequate productions, replete with boilerplate objections, have effectively impeded Plaintiffs' ability to acquire the information to which they are entitled. One of the most egregious examples involves patient brochures. Relying on a list produced by Defendant, Plaintiffs questioned Susan Lin, a 30(b)(6) regulatory designee, for more than an hour about a patient brochure that had been designated as a "final" version. Approximately three weeks after that deposition, and after Plaintiffs elicited damaging testimony about the brochure, Defendant produced a new list that excluded that very patient brochure from the list of "final" versions. Thus, it is unclear at this point whether that testimony will even be usable at trial.

Another example involves the 510(k) submission regarding the TVT-Secur product. Though clearly encompassed by both Rule 26 and Plaintiffs' First Request for Production of Documents, the submission was not produced before Ms. Lin's deposition. In fact, it was not produced until the witness brought the submission to the deposition from her office down the hallway from her office, near the end of the third day of the deposition. Plaintiffs, of course, were unable to make any use of these documents after that extremely late disclosure. These and other examples of Defendant's stonewalling are explained below.

What Plaintiffs are respectfully asking the Court to do is to follow well established precedent and deem that the Defendant's objections have been waived. Defendant then will not be able hide behind these objections and will be forced to fully and finally answer discovery,

which has been outstanding for nearly a year. For the reasons explained below, and in Plaintiffs' initial motion, the Court should grant Plaintiffs' Motion to Compel.

II. None of Defendant's Response Arguments Refutes Plaintiffs' Well-Supported Argument That Defendant Has Waived Its Discovery Objections.

A. Defendant Cites No Case Law That Supports the Approach It Has Taken.

In their Motion, Plaintiffs identified three independent bases upon which Defendant's unusual method of objecting and partially responding has waived its right to raise any objections, citing several cases in support of the argument. (Pl. Mot. at 9-11). In response, Defendant cites only one case, *Kelly v. FedEx Ground Package System, Inc.*, No. 3:10-cv-01265, 2011 WL 2582517 (S.D. W. Va. June 29, 2011). That case does nothing to help Defendant's position.

In *Kelly*, this Court wrote that “[m]utual knowledge of all of the relevant facts gathered by both parties is essential to proper litigation.” *Id.* at *1 (citing *Hickman v. Taylor*, 329 U.S. 495 (1947)). Further, “a party should not be left in the position of doubting the thoroughness and implication of a discovery answer.” *Id.* Yet that is exactly the position Plaintiffs are in. As explained in more detail in Section III below, Plaintiffs have ample reason, based on the history of this litigation, to doubt the thoroughness of Defendant's responses. How could they not, when Defendant keeps producing new documents during, and even after, trial depositions have been completed, or worse yet, changing their minds as to whether or not the documents are “final” versions after damaging testimony has been elicited?

Rule 37 is clear: “[A]n evasive or incomplete disclosure, answer, or response must be treated as a failure to disclose, answer, or respond.” Fed. R. Civ. P. 37(a)(4) (emphasis added). Plaintiffs urge this Court to find that such equivocal responses, at a minimum, are evasive or incomplete, or worse, constitute a deliberate attempt to hide the ball with respect to what information has been produced and what information has been withheld. Either way,

Defendant's objections have been waived, as fully described in Plaintiffs' motion, and as virtually admitted in Defendant's response, which offers no legal authority to the contrary.

Because it is clear that all objections have been waived, the Court need not go through the specific objections addressed by Defendant in Section V of its Response.

B. Plaintiffs' Motion Is Much Broader Than Foreign Documents, But Defendant's Discovery Responses Are Clearly "Boilerplate."

Despite this Court's previous ruling in the AMS litigation, much of Defendant's response is devoted to arguing the alleged impropriety of foreign document discovery. While Plaintiffs consider this an important issue, the discovery problems in this litigation are much broader, as described in detail in Section III. As such, the Court should not view this Motion as primarily asserting a right to foreign discovery.

Nonetheless, the Court should reject Defendant's response arguments. First, the notion that these documents are undiscernable because they are not legally relevant is untenable. As Defendant admits, the standards of admissibility and discoverability are far different. (Def. Resp. at 5). Regardless, discovery has already proven the importance of these documents. For example, many years ago, in response to serious concerns about patient safety, Defendant changed the TVT labeling in Japan.¹ Although there is nothing biologically different about Japanese women,² Defendant failed to disclose this critical information to American women or their physicians. The same is true in Australia where Defendant withdrew the TVT-S product many years ago due to safety concerns.³ Because Defendant is a multinational concern, and the manufacturer of certain mesh products is in Europe, safety and material science information from around the globe is highly relevant. Of course, any objections have also been waived.

¹ See Bryan Lisa Dep. at 382:6-383:17, portions attached as Exhibit A; see also Ryuichi Urakawa e-mail to Patrice Napoda of July 23, 2009, attached as Exhibit B, at p. 3.

² Lisa Dep., Ex. A, at 386:6-20.

³ Robert Scherini e-mail to Sheri McCoy of Nov. 3, 2007, attached as Exhibit C.

The Court should further reject the assertion that the objections are not “boilerplate.” In their Motion, Plaintiffs provided examples of boilerplate responses. (Pl. Mot. at 7-8). For instance, one response is: “ambiguous, overly broad, unduly burdensome and seeks information that is not reasonably calculated to lead to evidence admissible at trial.” (*Id.* at 7). Another response claims that a request is “ambiguous, overly broad, and unduly burdensome.” (*Id.*). These assertions are not supported by any actual explanations or evidence.

The law, as cited previously by Plaintiffs, is clear. “The Rules anticipate that each objection to a discovery request will state precisely why the request is objectionable in view of the claims and defenses presented in this litigation.” *Mills v. E. Gulf Coal Preparation Co.*, 259 F.R.D. 118, 132 (S.D. W. Va. 2009). “Failure to state objections specifically in conformity with the Rules will be regarded as waiver of those objections.” *Id.* Again, Defendant has no counter for the legal authority submitted by Plaintiffs. As such, the Court should conclude that the objections have been waived for this alternative reason.

C. The Mere Production of a Privilege Log is Insufficient.

Defendant’s privilege log is not the focus of Plaintiffs’ argument, but Defendant’s production remains inadequate, despite Defendant’s recent production of a privilege log. The question of whether Defendant produced a privilege log is wholly separate from the question of whether its non-specific objections have waived Defendant’s right to object. Many of Defendant’s objections are in an “and/or” format, such as “attorney-client privilege and/or work product immunity,” or “confidential, proprietary business information and/or trade secrets.” (Pl. Mot. at 9). As explained, such “and/or” objections are improper.

Defendant’s entire response to that argument is premised on the notion that it fulfilled its obligations by producing a privilege log. But again, Defendant failed to address the legal

argument that such objections are waived if not made with specificity. *See, e.g., Hughes v. Sears, Roebuck & Co.*, No. 2:09-cv-93, 2010 WL 4978996, at *5 (N.D. W. Va. Dec. 2, 2010) (stating that asserting “the privilege and/or the work product doctrine … leaves the Court with the impression that Sears has not determined which privilege to assert so it attempts to reserve its right to both. This is outside both the Federal Rules of Civil Procedure and the Local Rules which require specificity.”). Defendant’s only case on the issue addressed a late and incomplete privilege log, rather than addressing whether discovery answers had effected a waiver. *First Sav. Bank, F.S.B. v. First Bank Sys., Inc.*, 902 F. Supp. 1356, 1363 (D. Kan. 1995). The court described the issue as one of discretion and noted that “[e]ven when the untimely objection is based on privilege, the court likewise may find a waiver.” *Id.* at 1360.

D. Answers That Simply Relate Back to Produced Documents Must Be Specific.

Defendant further argues that it has fulfilled its duty on certain responses by simply telling the Plaintiffs that they already have the document. As explained, the rules require that the Defendant give Plaintiffs’ counsel “sufficient detail to permit [Plaintiffs] to locate and to identify, as readily as can the party served, the records from which the answer may be ascertained.” Fed. R. Civ. P. 33(d).

Defendant argues that it should not have the burden to search the database where Plaintiffs can do so just as easily as Defendant. The problem with that argument is that Plaintiffs have no way of knowing if the document production complete when Defendant keeps springing new productions upon Plaintiffs during, and even after, trial depositions are completed—as described in more detail in Section III. This is not a situation where Plaintiffs are asking Defendant to do their searching for them. It is a situation where after countless hours of searching Plaintiffs cannot find the needles in the haystack, or they find the needles but discover

that Defendant has produced them in an unintelligible manner, or they find the needles but are later told that those particular needles are outdated. As such, Court intervention is needed.

III. Several Examples Demonstrate Why Plaintiffs Need Court Intervention; Late and Incomplete Productions Are Making It Nearly Impossible to Conduct Adequate Trial Depositions, or to Prepare Plaintiffs' Witnesses.

The impact on Plaintiffs and their counsel from Defendant's unfair discovery practices can be seen in their approach to a variety of document types. Defendant stated in its Response that Plaintiffs "have not given even one example of specific evidence that they believe has been kept from them." (Def. Br. at 2). While that statement is inaccurate, what follows are examples of how Defendant's untimely and incomplete productions have hampered Plaintiffs' discovery efforts with regard to several key document categories: patient brochures, 510(k) submissions, Instructions for Use ("IFUs"), Design History Files ("DHF"), Standard Operating Procedures ("SOPs"), Physician Training Materials, and Clinical Registries.

A. Patient Brochures

Patient Brochures are pamphlets describing a medical device and any risks and benefits associated with using the device, in language that is easy to understand, so that the patient can make an informed decision about using the device. They are created by medical device manufacturers and given to surgeons to encourage patients to use the medical devices.

More than a year ago, in the New Jersey consolidation, Defendant designated color, in-use versions of patient brochures for all Pelvic Organ Prolapse ("POP") products.⁴ Defense counsel also provided three copy review master indexes of marketing materials in the New Jersey litigation on April 12, 2012, which included some patient brochures.⁵ Though all patient

⁴ Letter from Kelly Crawford to Adam Slater 5-21-12 and attachments, which is Exhibit B to Letter from Tom Cartmell to Christy Jones of March 4, 2013, collectively attached hereto as Exhibit D.

⁵ See Copy Review Master Index, 1999-2004; 2005-2009; 2009-2011, attached as Exhibit E.

brochures were specifically requested by RFP in July 2012,⁶ on March 4, 2013, Plaintiffs again requested that a similar chart be produced for Stress Urinary Incontinence (“SUI”) patient brochures, for use in this MDL.⁷ Defendant then provided a list of copy-approved patient brochures on March 11.⁸ However, this chart was deficient because it failed to list the in-use dates for each brochure.⁹ Relying on this list, Plaintiffs’ counsel questioned numerous witnesses regarding patient brochures with the understanding that they were final, in-use versions. For instance, during the May 2 and 3 continuation of Ms. Lin’s deposition, Plaintiffs’ counsel spent more than an hour discussing a particular brochure from the chart that had been produced by Defendant. On May 24, Defense counsel produced an updated list of SUI patient brochures.¹⁰ This chart contains substantial additions and numerous deletions from the chart produced on March 11, and in fact it omitted the document Plaintiffs had relied on in questioning Ms. Lin.

In addition, Defendant still has not provided in-use dates for any of the SUI patient brochures. It is impossible for meaningful discovery to be completed when the final, in-use versions of the SUI patient brochures are constantly changing, and when it cannot be determined which version was in use at which time. This situation is particularly problematic given the large number of products involved in this litigation, which came onto the market at different times. The date that a patient brochure was first used, and the date on which it ceased being used, are crucial details that Plaintiffs need in order to prove what risk/benefit information was conveyed to them when they elected to have their SUI procedures, yet even today as bellwether depositions are ongoing, Plaintiffs do not have this information because of Defendant’s stone-walling.

⁶ See RPF No. 81, Exhibit B to Plaintiff’s Motion and Memorandum in Support, Doc. No. 585.

⁷ Letter from Cartmell to Jones of March 4, 2013, Exhibit D.

⁸ Letter from Ben Watson to Tom Cartmell of March 11, 2013, attached as Exhibit F.

⁹ Letter from Tom Cartmell to Donna Jacobs of March 19, 2013, attached as Exhibit G.

¹⁰ TVT/SUI Patient Brochures Index and Production Bates Range Chart Produced to Plaintiffs 05-24-13, attached as Exhibit H.

B. Instructions for Use

On March 4, 2013, Plaintiffs explained to Defense counsel certain deficiencies in their production of Instructions for Use (“IFUs”). IFUs are the instructions that accompany the medical device, for use by the treating physician in understanding how the device is to be implanted. Plaintiffs have relied on information produced in May 2012 as part of the New Jersey consolidation.¹¹ In that production, Defendant produced no final version of the TVT-Classic IFU for any date between clearance of the product in 1998 and January 16, 2001.¹² Additionally, three of the IFUs designated by Defendant as final, in-use versions clearly were not the final versions. They contained areas of missing text and other abnormalities.¹³ Plaintiffs requested that these key documents be reproduced and designated prior to Ms. Lin’s deposition. They were not. After two days of that deposition, Plaintiffs raised the same issues regarding the IFUs.¹⁴ Defendant then finally produced the missing documents.

After that deposition, Plaintiffs again raised the issue of the missing IFU for the TVT-Classic product.¹⁵ Defendant claimed it could not find the document. On May 24, 2013 Defendant finally produced the first new IFU chart since its defective production in the New Jersey litigation in May 2012. This chart now designates an in-use label for the TVT-Classic device between September 8, 2000 and December 26, 2003, as opposed to the previous chart which designates the first label as being in use from January 16, 2001 to “unavailable.”¹⁶ Even on this new chart, there is no label designated as in-use between clearance of the device on

¹¹ Letter from Crawford to Slater and attachments, which is Exhibit B to Letter from Cartmell to Jones, attached hereto as Exhibit D.

¹² Letter from Cartmell to Jones, Exhibit D.

¹³ *Id.*

¹⁴ Letter from Cartmell to Jacobs, Exhibit G.

¹⁵ E-mail from Andrew Faes to Ben Watson dated 05-10-2013, attached as Exhibit I.

¹⁶ IFU Index and Production Bates Range Chart produced to Plaintiffs on 05-24-13, attached as Exhibit J.

January 29, 1998 and September 8, 2000. Further, numerous versions of the TVT-O IFU that Plaintiffs have relied upon in depositions and for expert review have been changed.

Plaintiffs are entitled to know which patient brochures, and which instructions for use, were in use at which times. If Defendant truly does not know, with regard to a particular document, then Defendant should make that statement under oath, and Plaintiffs will proceed accordingly. But what is happening, and should not be allowed to continue, is Defendant constantly shifting its answers. Plaintiffs request documents, or information about documents, and Defendant claims to be unable to find what was requested, or to be looking for it.¹⁷ Then, documents are “found” at inopportune times for the Plaintiffs, such as in the middle of depositions. *See discussion infra*, Section III.C. Or, Defendant provides no information about when a document was in use, and then after it has been used in a deposition, declares that it was not the “in use” document at the relevant time. *See discussion supra*, Section III.A. Fairness, and the Federal Rules, dictate that Plaintiffs are entitled to a complete disclosure of documents—not eventually, but immediately, as trial depositions are ongoing.

C. 510(k) Submissions

Plaintiffs continue to have difficulty acquiring such basic documents as the complete and final 510(k) files for the TTV products at issue. Before Ms. Lin’s deposition, Plaintiffs informed Defense counsel that they did not believe they had the final 510(k) submission for the TTV-Secur product.¹⁸ Defendant simply stated that “just because this is a copy from a FOIA copy doesn’t mean it isn’t our submission,” and also provided an additional bates number which was

¹⁷ See March 11, 2013 Letter from Watson to Cartmell, Exhibit F (stating that Defendant was “still working to try to determine the in use dates” for the IFUs that had been produced); *see also* May 10, 2013 e-mail from Ben Watson to Andrew Faes, attached as Exhibit K (asserting that most Ethicon IFUs were in the possession of an unrelated third party).

¹⁸ E-mail from Tom Cartmell to Donna Jacobs of 3-6-13, attached as Exhibit L.

claimed to be the original submission.¹⁹ Plaintiffs proceeded with Ms. Lin's deposition on March 12 and 13, based on these assurances. During Ms. Lin's deposition, it became apparent from missing pages and other abnormalities that the TTVT-Secur and TTVT-O submissions were incomplete. After the first two days of the deposition, Defense counsel acknowledged that the 510(k)s for these products were not the original submissions and promised to obtain the actual copies.²⁰ Defendant produced new copies on March 29.²¹

Ms. Lin's deposition then resumed on May 2. Late on the third day, she brought copies of the 510(k)s from the central regulatory file room, located just down the hall from where she works. At the conclusion of the third day, Plaintiffs were given an opportunity to examine the documents. A number of them differed substantially from versions of the documents produced previously, and nearly all of them differed at least slightly.²² One change was the addition of 17 substantive pages within the TTVT-Classic 510(k), a subject Plaintiffs had already covered with Ms. Lin during the first two days of her deposition. While Plaintiffs were provided copies of some of these documents after the first day of Ms. Lin's deposition, only one of these documents has been produced in an ESI-complaint, bates stamped format. It is nearly impossible for the Plaintiffs to effectively conduct trial depositions when such a basic, key document as the 510(k) submission for a particular product keeps changing.

D. Design History Files

The Design History Files ("DHF's") for the various TTVT devices are large, frequently non-continuous files, generally consisting of multiple documents and, in some cases, thousands of pages. Thus, Plaintiffs required a summary production chart designating which ranges were

¹⁹ Letter from Ben Watson to Tom Cartmell of March 7, 2013, attached as Exhibit M.

²⁰ Letter from Phil Combs to Tom Cartmell of March 18, 2013, attached as Exhibit N.

²¹ Letter from Phil Combs to Tom Cartmell of March 29, 2013, attached as Exhibit O.

²² Letter from Andrew Faes to Ben Watson of May 23, 2013, attached as Exhibit P.

applicable to which devices. Defendant provided the first such chart on January 28, 2013.²³ Dan Smith is Defendant's 30(b)(6) designee for design issues. A few days before Mr. Smith's deposition continued on June 4, Defense counsel said they would produce an updated copy of the "DHF tracker" spreadsheet at the beginning of the third day of the examination.²⁴ Plaintiffs requested that this new spreadsheet be produced before the deposition, not on the day of the deposition.²⁵ Just two days before the deposition resumed, Defense counsel finally provided an updated copy of this spreadsheet, which added and deleted several pages from the version relied on by Plaintiffs during the first and second day of questioning in May.²⁶

In addition, just four days before the deposition resumed Defense counsel changed Mr. Smith's designation, stating that he would no longer testify as to financial compensation of consultants.²⁷ Further, Defendant did not produce a list of said consultants until the third day of the deposition. Plaintiffs have requested that the Defendants confirm that the production of the Design History Files for the devices is now complete,²⁸ but Defendant has been unwilling to do so.

E. Standard Operating Procedures

Plaintiffs have requested all policies and procedures relevant to the TTV products. Instead of simply identifying and producing these policies, as Defendant clearly is in the best position to do, Defense counsel requested a meet and confer, which occurred on March 22, 2013. On that call, Mr. Cartmell requested that Defense counsel produce an index of all Standard Operating Procedures ("SOPs") for Plaintiffs' review. On March 28, defense counsel provided a

²³ TTV DHF and eDHF tracker as of 01-28-2013, attached as Exhibit Q.

²⁴ E-mail from Tom Cartmell to Phil Combs and Chad Hutchinson of 06-01-13, attached as Exhibit R.

²⁵ *Id.*

²⁶ E-mail from Phil Combs to Tom Cartmell of 06-02-13, with attachment, attached as Exhibit S.

²⁷ E-mail from Chad Hutchinson to Tom Cartmell of 5-31-13, attached as Exhibit T.

²⁸ E-mail from Andrew Faes to Ben Watson of 5-9-13, attached as Exhibit U.

partial list of all SOPs.²⁹ To date, Defendant has not produced a complete list, despite repeated requests from the Plaintiffs, beginning with an April 23 letter that listed specific documents for which Plaintiffs were requesting that SOPs be produced.³⁰ The SOPs requested were eventually produced between May 10 and May 14, but they were produced outside of the ESI protocol and had production errors in approximately 25% of the production.³¹ These productions were the first that provided each revision for each SOP requested, as well as a date revision history showing in-use dates for each policy. In other words, until mid-May, Plaintiffs had no way of knowing which policy was in effect at which time. This information was provided only after Plaintiffs elicited testimony from several witnesses that such information was easily available to Ethicon employees.³²

Still, even when requested SOPs are produced, they are still frequently missing key items such as appendices,³³ or they are not provided for all relevant time periods, such as the when the TTVT-Classic was first put on the market.³⁴ While Defendant has raised technical issues regarding identification and production of standardized policies,³⁵ these issues should have been raised months ago, and certainly prior to the start of scheduled 30(b)(6) depositions.

For all of these reasons, Defendant's untimely, incomplete, and often undecipherable productions, replete with boilerplate objections, have severely curtailed Plaintiffs' ability to

²⁹ Letter from Chad Hutchinson to Tom Cartmell of March 28, 2013, attached as Exhibit V.

³⁰ Letter from Tom Cartmell to Chad Hutchinson of April 23, 2013, attached as Exhibit W.

³¹ See Letter from Andrew Faes to Kari Sutherland of May 24, 2013; letter from Andrew Faes to Ben Watson of June 5, 2013, collectively attached as Exhibit X.

³² E-mail from Tom Cartmell to Ben Watson of 04-26-13, attached as Exhibit Y.

³³ E-mail from Andrew Faes to Ben Watson of 06-01-13, attached as Exhibit Z.

³⁴ E-mail from Andrew Faes to Ben Watson 06-02-2013, attached as Exhibit AA. PR800-011 is a key policy regarding the risk management process for medical devices at Ethicon. The defense was unable to identify and produce the policy in effect at the time of the development of the TTVT "classic" device prior to days 3 and 4 of their designee on design topics, and still have not done so.

³⁵ Letter from Ben Watson to Bryan Aylstock of May 22, 2013, attached as Exhibit BB.

obtain useful testimony from witnesses whom they likely will not be able to bring to trial, as well as their ability to prepare their own witnesses for depositions.

F. Physician Training Materials

Ethicon has stated through numerous witnesses already deposed in this litigation that complications from its mesh procedures can be minimized through “specialized training.” Professional Education Training can come in many forms, including written materials (such as text books, manuals, the IFU, and power point presentations), cadaver labs, surgical videos, and live surgeries with preceptors.

Plaintiffs requested Professional Education related documents and other training materials in their original requests for production back in July 2012.³⁶ On April 29, 2013, Mr. Watson did provide charts of copy review materials for TVT and Prosima but noted that these lists were not exhaustive, nor could he represent that these were final versions of the professional education materials that were actually used in training physicians. After another 10 days had elapsed, and another follow up email from Mr. Aylstock, Defendant still could not produce final version of the professional education materials.³⁷ Finally, after several additional follow up attempts,³⁸ and on the evening before the deposition of the director of professional education, Paul Parisi, an additional chart was provided which was represented to be the final copy approved professional education materials.³⁹ However, even this chart was not accurate because some of the “final” professional education materials had modifications and handwritten notes on them, and thus were clearly not final. After bringing these issues to the Defendant’s attention,

³⁶ See RFP No. 84, Exhibit B to Plaintiffs’ Motion and Memorandum in Support.

³⁷ See Ben Watson e-mail to Bryan Aylstock of April 29, 2013, attached as Exhibit CC, pp. 1-2.

³⁸ See E-mail string with Bryan Aylstock to Ben Watson e-mail of June 3, 2013, at top, attached as Exhibit DD.

³⁹ See TVT Professional Education Index, Produced to Plaintiffs on 06/04/13, attached as Exhibit EE.

Plaintiffs were advised again that the investigation was ongoing and everything would be done to get confirmation as quickly as possible.

G. Clinical Registries and Underlying Data

Medical Device Clinical Trial Registries are clinical trials conducted to collect safety and efficacy data relating to the use of a medical device. The goal of a clinical trial registry is to allow physicians to track patient outcomes in their practice in real time. The TVT World Wide Registry, for example, consisted of data from more than one thousand patients implanted with Ethicon's TVT devices across the world. This information is highly relevant and indeed may be critical to Plaintiffs' experts in formulating and supporting their opinions.

Plaintiff's requested data from "past, future, or potential studies and/or registries" in their initial requests for production back in July 2012.⁴⁰ Defendants have responded to Plaintiffs' requests with their boiler plate objections as described above and have also suggested that some, though not all, of these documents have already been produced.⁴¹ Defendants then indicated that it "believed" all of the TVT Registry Data had been produced.⁴² Plaintiffs know this is not the case. These documents have also been the subject of much debate in the New Jersey litigation, and Plaintiffs learned, in January 2013 at the deposition of Aaron Kirkemo, that a TVT registry existed and was maintained by Dr. Vincent Lucente.⁴³ When New Jersey counsel renewed their request for the registry productions, they were informed in a letter from Kelly Crawford, dated May 15, 2013, that no one knows what happened to the data, and that the only person involved in managing the data had died in a car accident a few weeks before the date of the letter.⁴⁴ Since these materials were clearly requested back in July 2012, the failure to produce them timely is a

⁴⁰ See RFP No. 54, Exhibit B to Plaintiffs' Motion and Memorandum in Support.

⁴¹ See Watson e-mail to Aylstock of April 29, 2013, Exhibit CC, pp. 1-2.

⁴² Ben Watson e-mail to Bryan Aylstock of May 10, 2013, attached as Exhibit FF.

⁴³ Case Management Conference in New Jersey litigation, portions attached as Exhibit GG, at 19:1-22:22.

⁴⁴ Kelly Crawford Letter to Adam Slater of May 15, 2013, attached as Exhibit HH, at pp. 3-4.

serious discovery violation. These same concerns were addressed at the May 22, 2013, Case Management Conference in New Jersey by the Honorable Carol Higbee, who ordered that this information be produced. Had Defendant not used these boilerplate objections, these documents would have been produced months ago. At a minimum, Defendant would have had to admit that these materials existed.

IV. Conclusion

For these reasons, as well as those expressed in the Plaintiffs' Motion and accompanying Memorandum, Plaintiffs respectfully request that the Court grant Plaintiffs' Motion to Compel. Plaintiffs further request that the Court conclude that Defendant's objections have been waived.

Respectfully Submitted,

/s/ Thomas P. Cartmell

Thomas P. Cartmell
WAGSTAFF & CARTMELL LLP
4740 Grand Avenue, Suite 300
Kansas City, Missouri 64112
Phone: (816) 701-1100
Fax: (816) 531-2372
tcartmell@wcllp.com

D. Renee Baggett
Bryan F. Aylstock
AYLSTOCK, WITKIN, KREIS
AND OVERHOLTZ, PLC
17 E. Main St., Suite 200
Pensacola, FL 32563
Phone: 850-202-1010
Fax: 850-916-7449
Rbaggett@awkolaw.com
Baylstock@awkolaw.com

Attorneys for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that on this 11th day of June, 2013, I electronically filed the foregoing document, using the Court's CM/ECF filing system, thereby sending notice of said filing to all counsel of record for this matter.

/s/ Thomas P. Cartmell

Attorney for Plaintiffs

INDEX OF EXHIBITS

Exhibit A: Bryan Lisa Deposition, portions to be filed under seal

Exhibit B: Ryuichi Urakawa e-mail to Patrice Napoda of July 23, 2009, to be filed under seal

Exhibit C: Robert Scherini e-mail to Sheri McCoy of Nov. 3, 2007, to be filed under seal

Exhibit D: Letter from Tom Cartmell to Christy Jones of March 4, 2013, with exhibits

Exhibit E: Copy Review Master Index, 1999-2004; 2005-2009; 2009-2011

Exhibit F: Letter from Ben Watson to Tom Cartmell of March 11, 2013

Exhibit G: Letter from Tom Cartmell to Donna Jacobs of March 19, 2013

Exhibit H: TVT/SUI Patient Brochures Index and Production Bates Range Chart Produced to Plaintiffs 05-24-13, to be filed under seal

Exhibit I: E-mail from Andrew Faes to Ben Watson dated 05-10-2013

Exhibit J: IFU Index and Production Bates Range Chart produced to Plaintiffs on 05-24-13, to be filed under seal

Exhibit K: E-mail from Ben Watson to Andrew Faes dated May 10, 2013

Exhibit L: E-mail from Tom Cartmell to Donna Jacobs of March 6, 2013

Exhibit M: Letter from Ben Watson to Tom Cartmell of March 7, 2013

Exhibit N: Letter from Phil Combs to Tom Cartmell of March 18, 2013

Exhibit O: Letter from Phil Combs to Tom Cartmell of March 29, 2013

Exhibit P: Letter from Andrew Faes to Ben Watson of May 23, 2013

Exhibit Q: TVT DHF and eDHF tracker as of 01-28-2013

Exhibit R: E-mail from Tom Cartmell to Phil Combs and Chad Hutchinson of 06-01-13

Exhibit S: E-mail from Phil Combs to Tom Cartmell of 06-02-13, with attachment

Exhibit T: E-mail from Chad Hutchinson to Tom Cartmell of 5-31-13

Exhibit U: E-mail from Andrew Faes to Ben Watson of 5-9-13

Exhibit V: Letter from Chad Hutchinson to Tom Cartmell of March 28, 2013

Exhibit W: Letter from Tom Cartmell to Chad Hutchinson of April 23, 2013

Exhibit X: Letter from Andrew Faes to Kari Sutherland of May 24, 2013; letter from Andrew Faes to Ben Watson of June 5, 2013

Exhibit Y: E-mail from Tom Cartmell to Ben Watson of 04-26-13

Exhibit Z: E-mail from Andrew Faes to Ben Watson of 06-01-13

Exhibit AA: E-mail from Andrew Faes to Ben Watson 06-02-2013

Exhibit BB: Letter from Ben Watson to Bryan Aylstock of May 22, 2013

Exhibit CC: Ben Watson e-mail to Bryan Aylstock of April 29, 2013

Exhibit DD: E-mail string with Bryan Aylstock to Ben Watson e-mail of June 3, 2013, at top

Exhibit EE: TTV Professional Education Index, Produced to Plaintiffs on June 4, 2013, to be filed under seal

Exhibit FF: Ben Watson e-mail to Bryan Aylstock of May 10, 2013

Exhibit GG: Case Management Conference in New Jersey litigation, portions attached

Exhibit HH: Kelly Crawford Letter to Adam Slater of May 15, 2013